

Appl. No.: 09/554,386
Group Art Unit: 1616
Applicants' Response to Paper No. 24

REMARKS

Claims 11-30 are currently pending in the present application.

The Obviousness Type Double-Patenting Rejection

In Paper No. 24, the Examiner provisionally rejects claims 11-30 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 11-30 of copending U.S. Patent Application No. 09/554,387 of Fabry (hereinafter referred to as "the copending application"). The Examiner contends that while the conflicting claims are not identical, "they are not patentably distinct from each other because presently claimed invention is drawn to method of reducing serum cholesterol content in mammals by providing a composition of phytosterol ester composition, which is considered obvious over the claimed invention of the said copending application." (See, Paper No. 24, pp. 2-3). On this basis, the Examiner again argues that the instant claims would have been obvious over the claims of the copending application.

Applicants strenuously, but respectfully traverse the Examiner's rejection and the arguments and contentions set forth in support thereof because the claims of the copending application fail to satisfy the criteria necessary to establish *prima facie* obviousness, or in this case, sustain a rejection based upon obviousness-type double patenting.

To begin with, the presently claimed invention is directed to methods of reducing serum cholesterol content in a mammal, wherein said methods comprise: (i) providing a hypocholesteremic preparation comprising at least one phytosterol ester of a conjugated fatty acid having from about 6 to about 24 carbon atoms; and (ii) administering the hypocholesteremic preparation to a mammal in an amount effective to reduce serum cholesterol content in the mammal.

In contrast, the claims of the copending application are directed to methods of reducing serum cholesterol content in a mammal, wherein said methods comprise: (i) providing a hypocholesteremic preparation comprising at least one component (a) selected from the group consisting of phytosterols and phytosterol esters and at least one component (b) selected from conjugated fatty acids having from about 6 to about 24 carbon atoms and

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glycerides of conjugated fatty acids having from about 6 to about 24 carbon atoms; and (ii) administering the hypocholesteremic preparation to a mammal in an amount effective to reduce serum cholesterol content in the mammal.

Applicants respectfully submit that the claims of the instant application and the claims of the copending application are patentably distinct. In the claims of the instant application a hypocholesteremic preparation comprising a conjugated fatty acid ester of a phytostenol is administered to a mammal. However, in the claims of the copending application a hypocholesteremic preparation comprising two separate components is administered to a mammal. In the copending application, a preparation comprising a phytostenol compound AND a separate conjugated fatty acid component is administered. This is different and distinct from the instantly claimed method in which a preparation comprising a phytostenol ester OF a conjugated fatty acid is administered.

Clearly, to achieve the claimed method from the teachings of the copending application, one would need to actively choose to react the two separate components of the preparation in the claims of the copending application to synthetically prepare a phytostenol ester of a conjugated fatty acid. Moreover, even if one were to somehow opt to react the two components claimed in the copending application to prepare the ester, which reaction would require catalysis, temperature, pressure, removal of water or a combination of two or more of these (none of which is taught or suggested in the copending application), the result would be an ester, not the combination of separate components claimed in the copending application.

Applicants respectfully submit that the claims of the instant application and those of the copending application are patentably distinct, and that no improper timewise extension of the right to exclude would result from the patenting of the instant claims and those of the copending application. Accordingly, reconsideration and withdrawal of the rejection of claims 11-30 under the judicially created doctrine of obviousness type double-patenting are respectfully requested.

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The Rejections Under 35 U.S.C. §103(a)

In Paper No. 24, the Examiner rejects claims 11-30 under 35 U.S.C. §103(a), as obvious over U.S. Pat. No. 4,588,717 of Mitchell (hereinafter referred to as "Mitchell"), U.S. Pat. No. 4,879,312 of Kamarei, *et al.* (hereinafter referred to as "Kamarei"), and International Publication No. WO92/19640 of Miettinen, *et al.* (hereinafter referred to as "Miettinen"). Applicant respectfully notes that International Publication No. WO92/19640 is the equivalent of the Miettinen reference (EP0594612) previously relied upon by the Examiner in the rejection that was withdrawn prior to the filing of the Request for Continued Examination filed in the instant application on March 24, 2003.

Applicant strenuously, but respectfully, traverses the Examiner's rejection and the arguments and contentions set forth in support thereof, for the following reasons. Miettinen fails to teach the use of a phytostenol ester of a *conjugated* fatty acid to reduce serum cholesterol in a mammal. Neither Mitchell or Kamarei teaches or suggests the use of a phytostenol ester of a *conjugated* fatty acid. As Applicant has previously argued and as accepted by the Examiner through the withdrawal of the previous rejections based upon Miettinen and other secondary references, a teaching of polyunsaturation DOES NOT equate to a teaching of conjugation.

The Examiner has cited Mitchell and Kamarei for the teaching of the use of linoleic acid and polyunsaturated acids (such as eicosapentanoic acid "EPA" and docosahexanoic acid "DHA"), respectively. However, as pointed out to the Examiner previously with respect to the teachings of Miettinen concerning polyene acids, polyunsaturation does not mean conjugation. (See, Applicant's Response After Final submitted on November 5, 2001, pp. 6-7).

There is no teaching or suggestion in any of the three cited references to administer a phytostenol ester of a *conjugated* fatty acid to a mammal to reduce serum cholesterol. Moreover, there is no teaching in any of the three references which would motivate one of ordinary skill in the art to use phytostenol ester of a conjugated fatty acid. Finally, given the lack of any teaching or suggestion of conjugated fatty acid esters of phytostenol compounds, and given the lack of any teaching or suggestion motivating such a modification of the prior art, one

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of ordinary skill in the art would not have a reasonable expectation of success, based upon the cited art.

Accordingly, Applicant submits that the Examiner has failed to establish a *prima facie* case of obviousness, as none of the three criteria necessary to establish a *prima facie* case of obviousness has been satisfied. Thus, Applicant respectfully requests withdrawal of the rejection based upon Mitchell, Karamel and Miettinen.

In Paper No. 24, the Examiner also rejects claims 11-30 under 35 U.S.C. §103(a), as obvious over the combined teachings of Miettinen and Mitchell. Applicant strenuously, but respectfully, traverses the Examiner's rejection and the arguments and contentions set forth in support thereof. The combination of any two or three of the references cited in the previous rejection fails to obviate the claimed invention as NONE of the references teaches or suggests CONJUGATED fatty acids for the preparation of phytosterol esters. Thus, Applicant respectfully requests withdrawal of the rejection based upon Miettinen and Mitchell.

In view of the remarks set forth above, Applicant submits that all pending claims patentably distinguish over the prior art of record and known to Applicant, either alone or in combination. Accordingly, reconsideration, withdrawal of the rejections and a Notice of Allowance for all pending claims are respectfully requested.

Respectfully submitted,

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January 13, 2005 By: [Signature]
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